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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,468	08/05/2003	H. Gene Hawkins	5490-000316	6819
27572	7590	12/06/2005		
HARNESSE, DICKEY & PIERCE, P.L.C. P.O. BOX 828 BLOOMFIELD HILLS, MI 48303			EXAMINER LUONG, SHIAN TINH NHAN	
			ART UNIT	PAPER NUMBER
			3728	

DATE MAILED: 12/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/634,468

Applicant(s)

HAWKINS, H. GENE .

Examiner

Shian T. Luong

Art Unit

3728

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 September 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 6, 11 and 14-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-10, 12 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/5/04, 12/3/04</u> . | 6) <input type="checkbox"/> Other: _____ |

Election/Restrictions

1. Claims 6,11 and 14-38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Group and Species , there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement.

Applicant argues that the subject matter defined within all the groups of claims are similar and the field of search for each group should be essentially coextensive. However, the standard for requiring a restriction between these two different groups is that the use as claimed can be practiced with a materially different product or the product as claimed can be used in a materially different process of using that product. In the instant case, the product as claimed can be used in a materially different process without the second sealing device and an outer container. The restriction is therefore proper and made Final.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term “the third container” lacks proper antecedent basis. Appropriate correction is required.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-3, 5, 7-9, 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Admitted Prior Art in view of Ronk (US 5,951,160) and Reprogenesis (WO 01/08630).

Admitted Prior Art discloses the use of donor bone particles called allograft in a surgical procedure to promote bone growth. The allograft is usually stored in a negative pressure in order to prolong their shelf-life. Admitted Prior Art does not show the container that stores the allograft and an outer container. Ronk discloses an apparatus for mixing and delivering bone cement such as bone graft material from one container to another container for mixing. The first container has a first opening and a second opening. A first sealing device is a valve 26 that removeably coupled to the first container through a leur fitting 28. A second sealing device 56 coupled to the first container and seals the second opening. The second sealing device is adapted to slidingly translate within the chamber. The first and second sealing devices define a chamber. The first container is a syringe and is adapted for direct application of the graft material to a surgical site. Reprogenesis also teaches the storage of at least one container within an outer container as shown in Figure 1A, 4, 11. The outer container maybe a tray or a bag. Accordingly, in view of the teachings from Ronk and Reprogenesis, it would have been obvious to store the allograft material into the syringe to facilitate surgical procedure and yet keep the material in a sealed area prior to usage.

Art Unit: 3728

6. Claims 4 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references applied above with respect to claim 1, further in view of Official Notice.

With regard to claim 4, it is not clear whether the valve is a vented valve. However, Ronk teaches that one skilled in the art will recognize various other valve or closure mechanism may be used. In addition, Official Notice is taken of the use of valve of various types such as vented valve for sealing purpose. It would have been obvious to apply vented valve in the even Ronk does not disclose a vented valve.

With regard to claim 10, the container may be placed in a vacuum bag as it is conventionally done in the container art.

7. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references applied above with respect to claim 1, further in view of Safabash et al. (US 5,908,054).

Admitted Art does not disclose a second syringe as required in claim 13. However, Safabash et al. teaches a fluid dispersion and delivery assembly 49 with first and second syringes. The solution in the first syringe is mixed with the second syringe. After the mixture, one of the syringes is dismounted and may dispense the material to a desired site. Hence, it would have been obvious to use a second syringe to allow the user to dispense the mixed material from either the first or the second syringe.

8. Claims 1-3, 5, 7-9, 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ronk in view of Admitted Prior Art and Reprogenesis (WO 01/08630). Ronk discloses an apparatus for mixing and delivering bone cement such as bone graft material from one container to another container for mixing. The first container has a first opening and a second opening. A first sealing device is a valve 26 that removeably coupled to the first container through a leur

Art Unit: 3728

fitting 28. A second sealing device 56 coupled to the first container and seals the second opening. The second sealing device is adapted to slidably translate within the chamber. The first and second sealing devices define a chamber. The first container is a syringe and is adapted for direct application of the graft material to a surgical site. Ronk does not disclose an outer container and the negative pressure. However, Admitted Prior Art discloses the use of donor bone particles called allograft in a surgical procedure to promote bone growth. The allograft is usually stored in a negative pressure in order to prolong their shelf-life. Reprogenesis also teaches the storage of at least one container within an outer container as shown in Figure 1A, 4, 11. The outer container maybe a tray or a bag. Accordingly, in view of the teachings from Ronk and Reprogenesis, it would have been obvious to store the allograft material into the syringe to facilitate surgical procedure and yet keep the material in a sealed area prior to usage.

9. Claims 4 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references applied above with respect to claim 1, further in view of Official Notice.

With regard to claim 4, it is not clear whether the valve is a vented valve. However, Ronk teaches that one skilled in the art will recognize various other valve or closure mechanism may be used. In addition, Official Notice is taken of the use of valve of various types such as vented valve for sealing purpose. It would have been obvious to apply vented valve in the even Ronk does not disclose a vented valve.

With regard to claim 10, the container may be placed in a vacuum bag as it is conventionally done in the container art.

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Art Unit: 3728

does not disclose a second syringe as required in claim 13. However, Safabash et al. teaches a fluid dispersion and delivery assembly 49 with first and second syringes. The solution in the first syringe is mixed with the second syringe. After the mixture, one of the syringes is dismantled and may dispense the material to a desired site. Hence, it would have been obvious to use a second syringe to allow the user to dispense the mixed material from either the first or the second syringe.

Conclusion

11. Telephone inquiries regarding the status of applications or other general questions, by persons entitled to the information, should be directed to the group clerical personnel and not to the examiners. In as much as the official records and applications are located in the clerical section of the examining groups, the clerical personnel can readily provide status information without contacting the examiners, M.P.E.P. 203.08.

If in receiving this Office Action it is apparent to applicant that certain documents are missing, e.g., copies of references cited, form PTO-1449, form PTO-892, etc., requests for copies of such papers should be directed to Erica Miller at (571) 272-4370. For applicant's convenience, the official FAX number is (571) 273-8300. This practice may be used for filing papers not requiring a fee. It may also be used for filing papers which require a fee by applicants who authorize charges to a PTO deposit account. Please identify Examiner Luong of Art Unit 3728 at the top of your cover sheet of any correspondence submitted. Inquiries concerning the merits of

Art Unit: 3728

the examination should be directed to Shian Luong whose telephone number is (571) 272-4557.

The examiner can normally be reached on M-H from 7:00am to 4:00pm EST.

STL

November 9, 2005

Primary Examiner


Shian Luong

Art Unit 3728